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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,456	07/03/2001	Carl Johan Friddle	LEX-0198-USA	8160
24231	7590	10/29/2004	EXAMINER	
LEXICON GENETICS INCORPORATED 8800 TECHNOLOGY FOREST PLACE THE WOODLANDS, TX 77381-1160			HAYES, ROBERT CLINTON	
			ART UNIT	PAPER NUMBER

1647

DATE MAILED: 10/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/898,456

Applicant(s)

FRIDDLE ET AL.

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5 and 9-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5 and 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. The response filed on 8/16/04 has been entered.
2. Applicants' arguments filed 8/16/04 have been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claim 11 stands rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, for the reasons made of record in Paper No: 20040204.

In contrast to Applicant's assertions on page 2 of the response, each application is examined according to its own merits, whether or not "**thousands** of patents directed to host cells" have been issued. Thus, Applicant's arguments are moot.

It is noted that Applicant has chosen to ignore the Examiner's suggestion on how to obviate this rejection.

5. Claims 1, 5 & 9-11 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility, for the reasons made of record in Paper No: 20040204, and as follows.

Applicant argues on pages 10 of the response that “the presently claimed sequence shares greater than 97% identity at the amino acid level over nearly the entire length of SEQ ID NO: 7 with two [GenBank] sequences...”, and therefore, is a “Homo sapiens WNT8d precursor”, and cites *Raytheon v. Roper*, *In re Gottlieb*, *In re Malachowski*, *Hoffman v. Klaus*, *Carl Zeiss Stiftung v. Renishaw PLC*, *In re Langer*, the enablement decision of *In re Marzocchi*, *Juicy Whip Inc. v. Orange Bang Inc.*, *Brenner and Manson*, *Brooktree Corp. v. Advanced Micro Devices, Inc.*, *Cross v. Iizuka*, *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, *Diamond vs. Chakrabarty*, *In re Brana*, and the enablement decisions of *In re Angstadt and Griffin*, *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd*, and *In re Wands*. However, the issue is utility, and that WNT stands for “wingless-type MMTV integration site family member”, in which humans reasonably have no wings (i.e., as it relates to even beginning to establish a “specific” use). Third, as far as Applicant’s reference to Exhibit B concerning the teachings of Kelly et al., Hopper et al., and Nasevicius et al. establishing a “well established utility” for Wnt-8 polynucleotides, humans are mammals, and not zebrafish nor frogs. Nevertheless, the issue remains that *many* genes are putatively detectable “throughout embryogenesis”, have a possible “role in mesoderm patterning”, or “dorsoventral patterning”, respectively, as illustrated by Hoppler’s statement that “[w]e find the Wnt-8 and BMP-4 are indistinguishable in their abilities to induce expression of ventral genes”. Therefore, in contrast to Applicant’s assertions “the present situation [*does not*] exactly track Example 10 of the Revised Interim Utility Guidelines Training Materials”, because neither zebrafish nor *Xenopus* Wnt-8 encodes a DNA ligase (which alternatively does have a “specific” and “real world” utility, unlike the putative encoded Wnt-8b

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protein of the instant invention) and where neither the zebrafish nor *Xenopus* Wnt-8 protein has any known “*specific*” assayable activity with a known “use” that distinguishes it from any different encoded polypeptide; if such Wnt “transcripts” are even translated into proteins. In other words, no use for any of the exhibited Wnt-8b polynucleotides are reasonably known within the art, because expression “patterns” of such transcripts merely constitute an interesting observation seen during embryogenesis. Thus, Applicant’s arguments concerning these points and that “the role of Wnt8 in neural development has long been known to those of skill in the art” are simply incorrect.

Applicant then argues that “ ‘DNA chips’ clearly have utility”, and that the “present sequences are specific markers of human chromosome 5”, which also has nothing to do with establishing a “specific” utility for the polynucleotide of SEQ ID NO: 7, because the “utility” for DNA chips is not based upon the existence of the polynucleotide of SEQ ID NO: 7, and because many different nucleotide sequences can be “markers” of chromosome 5, in which “localizing the specific region of human chromosome 5 that contains the gene encoding the given polynucleotide (*sic*) [with no known utility] ...”, does not reasonably establish a “*specific*” utility for the polynucleotide of SEQ ID NO: 7, by definition. Likewise, an invitation for others to discover a “real world”/ “substantial utility” for the instant invention does not establish “substantial utility”, by definition. In other words, Applicant’s arguments concerning DNA chips, “all nucleic acids”, etc. are flawed, because it does address what *specific* distinguishable “use” exists for the polynucleotide of SEQ ID NO: 7, for the reasons indicated above, and for the reasons previously made of record.

Accordingly, because the proposed use of the Wnt8b polynucleotide of SEQ ID NO: 7 simply is a starting point for further research and investigation into potential practical uses of the polynucleotide of SEQ ID NO: 7, the instant claims have no specific nor substantial utility, consistent with that held by the court in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966):

“The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility”, “[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field”, and “a patent is not a hunting license”, “[i]t is not a reward for the search, but compensation for its successful conclusion.”

Thus, Applicant’s arguments that “holding Applicants to a different standard of utility would be arbitrary and capricious, and like other clear violations of due process, cannot stand” is clearly misplaced, and has no merit. Again, see the Utility Guidelines in MPEP 2107.

6. Claims 1, 5 & 9-11 stand also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, for the reasons made of record in Paper No: 20040204.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.
October 21, 2004

ROBERT C. HAYES, PH.D.
PATENT EXAMINER



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